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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,423	05/10/2005	Yasuo Hayashi	2005_0747A	4714
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WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021				LEA, CHRISTOPHER RAYMOND
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,423	<b>Applicant(s)</b> HAYASHI ET AL.
	<b>Examiner</b> Christopher R. Lea	<b>Art Unit</b> 4161

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-38 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-38 is/are rejected.  
 7) Claim(s) 6 is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 10 May 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/10/2005</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

This application is a 371 (national stage application) of PCT/JP03/15338.

Claims 1-38 are pending. Claims 1-38 are under examination.

***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

2. The information disclosure statement(s) (IDS) submitted on May 10, 2005, was filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Objections***

3. Claim 6 is objected to because of the following informalities: Claim 6 recites "... characterized in that **one resin film to be delaminated** in said **one resin film to be delaminated** in said resin film delaminating and removing step..." which is redundant. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 & 17 recite the limitation "...in a direction substantially conforming to a tangential direction ..." which is indefinite. How close to a tangential direction must the direction be to substantially conform? Since claims 5-16 & 18-38 ultimately depend from claims 1-4, claims 5-16 & 18-38 are also rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roreger et al. (WO document 02/51815 (German) using US Patent 6,818,087 as translation) in view of Nogami (WO document 02/87622 (Japanese) using US PreGrant Publication 2004/0137040 as translation).

#### **Applicant claims**

Applicant claims a method and apparatus for manufacturing a multilayer edible film composition for administering an active agent.

#### **Determination of the scope and content of the prior art (MPEP 2141.01)**

Roreger et al. teach, as a whole, a method and apparatus for manufacturing a layered film composition containing an active agent.

Claim 1: Roreger et al. teach uniting two base material layers together under pressure (column 5, lines 65 through column 6, line 1) using pressure rollers (element 13 in figure 1). Roreger et al. teach peeling (delaminating) a protective layer, such as paper, plastic (resins) or textiles, off of the base material layers (column 4, lines 37-49).

Determining the arrangement of the delaminating apparatus (substantially conforming to a tangential direction) is within the purview of the skilled artisan.

Claim 2: Roreger et al. teach uniting two base material layers together under pressure (column 5, lines 65 through column 6, line 1) using pressure rollers (element 13 in figure 1). Roreger et al. teach peeling (delaminating) a protective layer, such as paper, plastic (resins) or textiles, off of the base material layers (column 4, lines 37-49). Determining the arrangement of the delaminating apparatus (substantially conforming to a tangential direction) is within the purview of the skilled artisan. Repeating the steps of laminating another layer on and delaminating its protective cover would also be within the purview of a skilled artisan.

Claim 3: Roreger et al. teach uniting two base material layers together under pressure (column 5, lines 65 through column 6, line 1) using pressure rollers (element 13 in figure 1). Roreger et al. teach peeling (delaminating) a protective layer, such as paper, plastic (resins) or textiles, off of the base material layers (column 4, lines 37-49). Roreger et al. teach the base materials being provided on stock rolls (column 4, lines 37-49), which means the step of winding the layers onto a roll would be necessarily carried out. Determining the arrangement of the delaminating apparatus (substantially conforming to a tangential direction) is within the purview of the skilled artisan.

Claim 4: Roreger et al. teach uniting two base material layers together under pressure (column 5, lines 65 through column 6, line 1) using pressure rollers (element 13 in figure 1). Roreger et al. teach peeling (delaminating) a protective layer, such as paper, plastic (resins) or textiles, off of the base material layers (column 4, lines 37-49).

Roreger et al. teach the base materials being provided on stock rolls (column 4, lines 37-49), which means the step of winding the layers onto a roll would be necessarily carried out. Determining the arrangement of the delaminating apparatus (substantially conforming to a tangential direction) is within the purview of the skilled artisan. Repeating the steps of laminating another layer on and delaminating its protective cover would also be within the purview of a skilled artisan.

Claims 5-8, 25, & 26: Roreger et al. teach that the protective layers are treated with silicone to be rendered detachable (column 4, lines 37-49). Determining which sides of which compositions would receive this treatment is within the purview of the skilled artisan.

Claims 9 & 27-29: Roreger et al. teach the pressure of the laminating step is 2 to 10 bars (0.2 to 1 MPa) which is inside the claimed range (column 5, lines 62-65).

Claims 10, 12, 13, & 30-32: Roreger et al. teach thermally conditioning the laminating equipment (column 5, lines 60-61) to achieve a desired viscosity in the base material. Though Roreger et al. do not teach a temperature at which the laminating is accomplished, it would be within the purview of the skilled artisan to determine the optimum temperature to insure binding by routine experimentation.

Claim 11: Roreger et al. teach that after binding the layered composition is cooled to a temperature of 3 to 10°C (column 6, lines 55-57).

Claims 14 & 33-35: Roreger et al. teach a base material that is 36 and 80 µm thick (example, column 7, lines 1-16).

Claims 15 & 36-38: Roreger et al. teach that the base materials are self-supporting laminate films (example, column 7, lines 1-16).

Claim 16: Roreger et al. teach removing the protective layers (column 4, lines 37-49). Determining when to remove the protective layer and which layers to remove is within the purview of the skilled artisan.

Claims 17-19: Roreger et al. teach uniting two base material layers together under pressure (column 5, lines 65 through column 6, line 1) using pressure rollers (element 13 in figure 1). Roreger et al. teach peeling (delaminating) a protective layer, such as paper, plastic (resins) or textiles, off of the base material layers (column 4, lines 37-49) and onto winding rolls (element 6 in figure 1). Determining the arrangement of the delaminating apparatus (substantially conforming to a tangential direction) and the size of the delamination roll (winder) is within the purview of the skilled artisan.

Claim 20: Roreger et al. teach the unwinding rolls (elements 1a and 2a in figure 1) and the winding rolls (elements 5 & 6), and it would be within the purview of the skilled artisan to determine the size of the rolls through routine experimentation.

Claim 21-24: Roreger et al. teach that the composition can be cut after bonding (column 6, lines 58-60). The claims further describe a system for receiving the finished product and storing on a plurality of wheels. Roreger et al. teach a single wheel to receive the product (see figure 1, unlabeled element below 14) and the duplication of this element for each of the cut-down film compositions would be obvious to the skilled artisan.

**Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)**

The difference between Roreger et al. and the instant claims is that Roreger et al. do not expressly teach edible films. This deficiency in Roreger et al. is cured by the teachings of Nogami.

Nogami teaches, as a whole, a layered edible film composition for administering an active agent.

Claims 1-38: Nogami teaches making the layers by applying (coating) a solution and drying it (manufacturing example 1, paragraph 109). Nogami teaches the drug-containing layer is made of an edible polymer including cellulose and cellulose derivatives preferably hydroxypropylcellulose and hydroxypropylmethylcellulose phthalate (paragraph 54).

**Finding of *prima facie* obviousness  
Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the edible layered active agent composition of Nogami by a modified laminate composition-producing method and apparatus as taught by Roreger et al. and produce the instant invention. The skilled artisan would have been motivated to make the layered film compositions in this manner because Nogami suggests forming multilayer film compositions by making two halves of the composition and thermally fusing them under pressure (paragraph 108).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Double Patenting***

10. Applicant is advised that should claims 6 & 8 be found allowable, claims 25 & 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

***Conclusion***

Claims 1-38 are rejected. Claim 6 is objected to. No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571)270-5870. The examiner can normally be reached on Mon-Thu 7:30-5:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616